For IACUC Use Only: *IACUC No.:* *Date of Approval:*
Rev 2: December 2000

Check all that apply:
☐ Maj. Surv. Surgery ☐ Primates ☐ Cat. E studies ☐ Haz. Agents ☐ Dogs, cats or pigs

ANIMAL COMPONENT OF RESEARCH PROTOCOL (ACORP)
DRAFT

General Information

Note: Use a separate form for each species. DO NOT include individual appendices if they are not relevant to the protocol being described. Type an "x" in the box(es) next to your selection(s). Define all abbreviations the first time they are used. To add a row to a table, click inside one of the existing table cells, then select Table, Insert, Rows from the main menu of the program.

A. **ACORP Status.** Complete items A.1.- A.8. below; then proceed to item B.

1. Name of Principal Investigator:
2. VA Station Name and Number:
3. Proposal Title:
4. Animal Species covered by this ACORP (only one):
5. Funding Source. Indicate the source(s) of funds that will be used to perform these animal procedures once approved by the VA IACUC:
   - ☐ Department of Veterans Affairs
   - ☐ U. S. Public Health Service (e.g. NIH)
   - ☐ Private or Charitable Foundation. Identify:
   - ☐ University Departmental Funds. Identify University and Department:
   - ☐ Private Company. Identify:
   - ☐ Other. Identify:

6. Is this a new ACORP for a new project?
   - ☐ Yes. Proceed to item 7.
   - ☐ No. Answer A.6.a.-c. below.
     - a. Indicate the status of this ACORP below:
       - ☐ This is an unchanged, approved ACORP intended for a new funding source.
       - ☐ This is a revised ACORP with a new funding source.
       - ☐ This is a revised ACORP that reflects changes or additional, new studies.
       - ☐ This ACORP is submitted as a three-year (3-year) renewal.
       - ☐ Other. Please specify:
     - ☐ b. Previous ACORP title:
     - ☐ c. Previous IACUC approval number (VA and affiliate, if applicable):

7. Do you plan on performing the animal procedures described in this form even if you do not receive extramural VA, PHS, NSF, or other funding?
   - ☐ Yes.
   - ☐ No.

8. Indicate the type of animal use:
   - ☐ Research.
   - ☐ Teaching or Training.
   - ☐ Testing.
   - ☐ Sentinel animal use.
   - ☐ Breeding and colony management only; no experimental procedures.
   - ☐ Other. Please specify:

Proposal Overview

B. Using non-technical (lay) language that a senior high school student would understand, briefly describe how this research project might improve the health of people and/or other animals. A scientific abstract from a grant proposal is not acceptable. Once completed, proceed to item C.

C. **Experimental Design.**

1. Using non-technical (lay) language that a senior high school student would understand, describe the experimental design in no more than one or two paragraphs.

2. In language scientific colleagues outside of your discipline would understand, describe the experimental design for the animal experiments planned, and the sequence of events to reveal what happens to the animals. Include all procedures and manipulations, and explain why they must be performed. Give your best estimate of how many animals will undergo the procedures or manipulations described. For complicated experimental designs, a flow chart, diagram, or table is strongly recommended to help the IACUC understand what is proposed. Do not describe the details of surgical procedures, monoclonal antibody production, or behavioral training here. Such details are requested later in appendices. Once completed, proceed to item D.

D. Describe the characteristics of the selected species, strain, stock, mutant, or breed that justify its use in the proposed study. Consider such characteristics as body size, species, strain, breed, availability, data from previous studies, and unique anatomic or physiologic features. Once completed, proceed to item E.

Personnel

E. Give the names of all research staff expected to work with the animals in this study. For each person listed, describe their education, training, and experience with experimental animals in general AND describe their experience performing the exact procedures in the species described in this ACORP. This description must help IACUC members determine if all animal manipulations, including surgery, testing, and blood collection, are performed by individuals who are qualified to accomplish the procedures skillfully and humanely. A listing of academic degrees alone is not an adequate response. (Qualifications to perform euthanasia will be requested in item U.3. and need not be given here.) Once completed, proceed to item F.

F. If personnel do not have experience with the exact procedures described in this ACORP, how will they be trained, who will train them, and what are the training experiences or qualifications of the person(s) doing the training? If not applicable, enter “N/A”. Once completed, proceed to item G.

G. **Occupational Safety and Health.**

1. Have all personnel listed in item E. been enrolled in the Occupational Health and Safety Program for those with laboratory animal contact?
   ☐ Yes. Proceed to item G.2.
   ☐ No. If personnel have declined to participate, are enrolled in another equivalent program, or will enroll before studies commence, so indicate here and then proceed to item G.2.

2. Are there any non-routine measures such as special vaccines or additional health screening techniques that would potentially benefit research, husbandry, or veterinary staff participating in or supporting this project? Routine measures included in the Occupational Health and

Safety Program (vaccination for tetanus, rabies, and hepatitis B, and TB screening) need not be mentioned here.

☐ Yes. Describe them below; then proceed to item H.
☐ No. Proceed to item H.

Animal Information

H. Complete the following table; then proceed to item I.

Strain, Stock, Mutant, or Breed	Gender	Age/Size	Source (Vendor)	Health Status*

*For each strain, stock, mutant, or breed listed, provide information about the expected status of the animals:
-For rodents and rabbits, indicate specific-pathogen-free (SPF), gnotobiotic (germ-free or defined flora), conventional, feral, or other description.
-For dogs, cats, pigs, and other "large animals", indicate specific-pathogen-free (SPF), conditioned, conventional, feral, or other description.
-For non-human primates, indicate viral status (e.g., herpes B, SIV, etc.)
-Also indicate here if animals will be surgically altered by the vendor (e.g., ovariectomized rats).

I. Complete the tables below, assigning all requested animals by breed/strain/mutant to a USDA category of pain/distress. If you have difficulty determining the appropriate category, please contact the attending veterinarian or IACUC Chair for assistance. The same animal cannot be assigned to more than one USDA category. If several different procedures are planned, the animal should be placed in a category based on the most painful/distressful procedure. You are required by VA policy to describe planned procedures for the fourth and fifth years of a submitted VA grant even though, under PHS policy, the IACUC must perform a new review three years after the initial approval date. Once completed, proceed to item J.

USDA Category B: List by year the number of animals that will be bred or purchased for breeding, but not used for experiments. This includes breeders, young that cannot be used because of improper genotype or gender, and any other animals that will not have any research procedures performed on them or participate in research studies. If numbers cannot be determined exactly, estimate as closely as possible. (Note: If tail snips are necessary for genotyping, this category is not appropriate.)

Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5

USDA Category C: List, by year the number of animals that will undergo procedures that involve no or only very brief pain or distress, with no need for or use of pain relieving drugs. Examples include observational studies, most intravenous and parenteral injections of non-irritating agents, most blood collections from peripheral vessels, and the collection of cells and/or tissues from animals after euthanasia has been performed.

Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5

USDA Category D: List by year the number of animals that will undergo procedures involving potential pain or distress that is relieved by appropriate anesthetics, sedatives, or analgesics. Examples include major and minor surgery performed under anesthesia (survival or non-survival), tissue or organ collections prior to euthanasia, painful procedures performed under anesthesia (such as retro-orbital blood collection in rodents), prolonged restraint accompanied by tranquilizers or sedatives, and experiments involving infectious or other hazardous materials in animals that have provisions for immediate euthanasia if they become sick to effectively prevent pain and/or suffering. If an endpoint is used that involves significant pain or distress, consideration should be given to putting animals into Category E.

Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5

USDA Category E: List, by year, the number of animals that will undergo procedures in which pain or stress is NOT relieved with the use of anesthetics, analgesics, tranquilizers, or by euthanasia. Examples include studies in which animals are allowed to die without intervention (e.g. LD_{50}, mortality as an end-point), studies that allow endpoints that are painful or stressful, addictive drug withdrawals without treatment, pain research, and noxious stimulation.

Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5

TOTALS: Bring all totals for each year down, by breed/strain/mutant.

Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5

J. **Description of USDA Category D and E procedures**. Are any USDA Category D or E studies planned?

☐ No. Proceed to item K.
☐ Yes. Complete items J.1. and J.2.; then proceed to item K.

1. List and describe all category D procedures by filling out the table below. If no category D studies are proposed, enter "N/A" and proceed to item J.2. For any surgical procedures you will describe in Appendix 5, enter only a brief description in the "Procedure" column, then enter "See Appendix 5 for details."

Procedure	Frequency of monitoring after the procedure and how long animals will be monitored	Person(s) doing the monitoring	Analgesic, sedative, or anesthetic used, plus dose, route, and duration

2. Each year a report describing and justifying all category E procedures must be submitted by each facility to the USDA and the VA. If no category E studies are proposed, enter "N/A" and proceed to item K. Otherwise, describe each category E procedure, and justify completely why pain or distress relief cannot be provided for each procedure. Your description will be used in the USDA annual report. If animals will be allowed to experience natural death as a result of experimental procedures (e.g. infectious disease or oncology studies), or an endpoint is used that allows the animals to experience significant pain or distress, you must justify why

an alternate endpoint (such as weight loss, clinical signs, tumor size, etc.) prior to death or pain or distress can not be used. If animals will undergo category D procedures as well, describe them in item J.1. above.

K. Describe how the estimated number of animals needed for the experiments was determined. When appropriate, provide the number and type of experimental and control groups in each experiment, the number of experiments planned, and the number of animals in each group. The ILAR *Guide* states that whenever possible, the number of animals requested should be justified statistically. A power analysis is strongly encouraged to justify group sizes when appropriate. Once completed, proceed to item L.

Animal Housing and Care

L. **Laboratory Animal Veterinary Support**. Complete items L.1-L.3, then proceed to item M.

1. Give the name of the laboratory animal veterinarian responsible for providing adequate care to the animals that will be used along with their institutional affiliation.

2. VA Policy requires that a laboratory animal veterinarian be consulted during the planning stages of any procedure involving laboratory animals, before IACUC review. Give the name of the laboratory animal veterinarian consulted during the planning of procedures involving animals. As an alternative to an actual meeting, the veterinarian may perform a pre-review of the ACORP and provide comments to the PI so that the ACORP may be revised prior to IACUC review.

3. Give the date of the veterinary consultation (meeting date, or date written comments were provided by the veterinarian to the PI).

M. **Husbandry.**

1. Caging needs. To help the animal care staff with caging needs, please indicate the type of caging that you will need; then go on to question M.2:
   - ☐ Gnotobiotic (germ-free and defined flora) isolators
   - ☐ Biohazard or other special hazard containment caging
   - ☐ Sterile rodent microisolator caging, with filtered cage top
   - ☐ Non-sterile rodent microisolator caging, with filtered cage top
   - ☐ Standard rodent shoebox caging with no filter top
   - ☐ Standard non-rodent caging, appropriate for species
   - ☐ Other. Describe:

2. The ILAR *Guide for the Care and Use of Laboratory Animals* states that consideration should be given to housing social animals in groups whenever possible. Will social animals be housed singly?
   - ☐ Yes. Complete item M.3.
   - ☐ No. Proceed to item M.4.
   - ☐ Not Applicable; the species involved is not a social animal. Proceed to item M.4.

4. Please provide a justification for housing social animals singly; then proceed to question M.4.

4. The ILAR *Guide for the Care and Use of Laboratory Animals* recommends the use of contact bedding (i.e., shoebox or microisolator cages) instead of wire mesh floors for housing rodents. Will rodents be housed on suspended wire mesh floors or other flooring in which the animals do not rest on bedding?
   - ☐ Not applicable; this ACORP does not describe rodent use. Proceed to item M.6.

☐ No. All rodents will be housed in shoebox or other caging in which the animals rest directly on bedding. Proceed to item M.6.
☐ Yes. Proceed to item M.5.

5. Why is caging with wire mesh flooring necessary?

6. Indicate the appropriate response below:
   ☐ This ACORP does not address the use of dogs, primates, or transgenic mice. Proceed to item M.7.
   ☐ This ACORP addresses the use of dogs. Answer item M.6.a. below.
   ☐ This ACORP addresses the use of primates. Answer item M.6.b. below.
   ☐ This ACORP addresses the use of transgenic mice. Answer item M.6.c. below.

   a. Is there any scientific justification for excluding the dogs in this study from the institutional dog exercise plan required by USDA?
      ☐ No. Proceed to item M.7.
      ☐ Yes. Provide a scientific justification for excluding the dogs; then proceed to item M.7.

   b. Is there any scientific justification for excluding the primates from the institutional primate psychological enrichment plan required by USDA?
      ☐ No. Proceed to item M.7.
      ☐ Yes. Provide a scientific justification below for excluding the primates; then proceed to item M.7.

   c. Do the transgenic mice planned for use exhibit any characteristic clinical signs or abnormal behavior related to their genotype?
      ☐ No. Proceed to item M.7.
      ☐ Yes. Describe here, then proceed to item M.7.:

7. Will any cannulae, acrylic implants, venous catheters, or other similar medical devices be implanted into an animal such that the device extends chronically through the skin?
   ☐ No. Proceed to item N.
   ☐ Yes. Explain what wound management measures will be taken to minimize the chances of chronic infections around the device(s) where they penetrate the skin.

N. **Housing Sites**.

1. Will all animals purchased with VA or VA Foundation funds be housed only in VA facilities?
   ☐ Yes. Proceed to item N.2.
   ☐ No. Complete and attach ACORP Appendix 1, “Use of Non-VA Animal Facility”, then go to item N.2.

2. Give the VA location(s), inside or outside of the animal facility, where animals will be housed permanently or temporarily, then proceed to item O.

Experimental Procedures

O. **Antibody Production.** Will animals be used to produce monoclonal or polyclonal antibodies, or will existing hybridoma cell lines be injected into animals to harvest antibody?
   ☐ No. Proceed to item P.
   ☐ Yes. Complete and attach Appendix 2, “Antibody Production;” then proceed to item P.

P. **Test Substances.** Will test substances be administered to animals? For the purposes of this question, test substances are defined as materials administered to animals. This includes, but is not limited to, radioisotopes, toxins, antigen, pharmacological agents, infectious agents,

carcinogens or mutagens, biomaterials, prosthetic devices, and cells, tissues, or body fluids. (Note: The following substances do not need to be entered in Appendix 3 unless they are hazardous: routine pre- or post-operative drugs described in the Surgery Appendix [Appendix 5], antigens, adjuvants, hybridomas described in the Antibody Production Appendix [Appendix 2], and euthanasia agents entered in item U, Euthanasia.)

☐ No. Proceed to item Q.
☐ Yes. Complete and attach Appendix 3, "Test Substances;" then proceed to item Q.

Q. **Location of procedures.** Complete the table below, indicating where all non-surgical procedures will be performed. Be sure to include the sites of procedures such as radiography, fluoroscopy, computed axial tomography (CT), or magnetic resonance imaging (MRI) that may be performed outside the animal facility.

Non-surgical Procedure	Building and Room Number	Method of discreet transport, if required through non-research areas (enter N/A if not applicable)*

*Describe how animals will be transported to and from these sites. Transportation must be in accordance with the *Guide*, USDA regulations, and PHS policy in climate-controlled vehicles and sanitizable transport cages when appropriate. Transport through non-research areas must be discreet. Once completed, proceed to item R.

R. **Body Fluid, Tissue, and Device Collection.**

1. Will any body fluids, tissues, or devices be collected from animals AFTER euthanasia?
   ☐ No. Proceed to item R.2.
   ☐ Yes. List the fluids, tissues, and/or devices here; then proceed to item R.2.

2. Will any body fluids, tissues, or implanted devices or materials be collected from animals BEFORE euthanasia?
   ☐ No. Proceed to item S.
   ☐ Yes. Proceed to item R.3.

3. Is collection in live animals limited to blood collection associated with antibody production?
   ☐ No. Complete and attach Appendix 4, "Antemortem Specimen Collection." Then proceed to item S. If the body fluid, tissues, or devices are collected as a surgical procedure, please be sure to also describe these collections as part of the surgical protocol in the Appendix 5, "Surgery."
   ☐ Yes. Because blood collection associated with antibody collection is already described in Appendix 2, "Antibody Production", DO NOT complete Appendix 4, "Antemortem Specimen Collection." Proceed to item S.

S. **Surgery.** Will survival or non-survival surgery be performed?
   ☐ No. Proceed to item T.
   ☐ Yes. Complete and attach Appendix 5, "Surgery;" then proceed to item T.

T. **Endpoint Criteria.** What specific endpoint criteria will be used for determining when sick animals, both on and off study, will be euthanatized or otherwise removed from a study? Examples of appropriate criteria that should be considered include a weight loss limit as a percentage of initial or expected body weight, allowable durations of anorexia, allowable tumor size or total tumor burden expressed as a percentage of body weight, the presence of health problems refractory to

medical intervention, and severe psychological disturbances. Other criteria appropriate for the species under consideration should also be considered. When complete, proceed to item U.

U. **Euthanasia**. Will animals be euthanatized as part of the planned studies?

☐ No. Describe the final disposition of the animals here, then proceed to item U.4:
☐ Yes. Complete items U.1. - U.4. below; then proceed to item V.

1. Describe the exact method of euthanasia for each animal used. Include the agents used, dose (as applicable), and route of administration.

2. Justify any method that is not considered "acceptable" by the latest report of the AVMA Panel on Euthanasia. (More info- item U.2) If you are unsure how to answer, contact your veterinarian or IACUC for guidance. If all methods are considered acceptable by the Panel, enter "All methods meet AVMA Panel recommendations" below:

3. List the personnel who will perform euthanasia and indicate their training and experience with the method of euthanasia and the species involved. If personnel are not yet trained, indicate so and explain how they will be trained before performing euthanasia themselves.

4. Should the animal care staff find an animal dead, how should the carcass be handled (e.g. refrigerated or frozen), and should a member of your staff be contacted immediately?

V. **Special Procedures.** Are any experimental procedures or special husbandry procedures planned that are NOT described in the local standard operating procedures (SOP) manual or elsewhere in this ACORP? Special procedures can include special restraint practices (including non-human primate chairing), special animal health monitoring, special diets, caging, environmental control, exercise, environmental enrichment, means of identification, use of noxious stimuli, forced exercise, or behavioral manipulation.
☐ Yes. Complete and attach Appendix 6, "Special Husbandry and Procedures;" then proceed to item W.
☐ No. Proceed to item W.

Mandatory Considerations

W. **Consideration of Alternatives and the Prevention of Unnecessary Duplication.** Complete items W.1 through W.5 below; then proceed to item X. Keep copies of computer database search results in your files to demonstrate your compliance with the law if regulatory authorities or the IACUC should choose to audit your project.

1. Investigators must consider less painful or less stressful alternatives to procedures, and provide assurance that proposed research does not unnecessarily duplicate previous work. You should perform one or more database searches to meet these mandates unless compelling justifications can be made without doing so. Complete the table below for each database search you conduct to answer items W.2 through W.5 below. You must provide complete information in the first four columns of the table to comply with USDA Policy #12.

Name of the database (s)	Date performed	Period (years) covered by each search	Key words and/or search strategy used	Indicate below for which mandate each search was conducted by placing an "X" in the proper column			
				Alternative computer models or *in vitro* techniques (item W.2)	Alternative use of less-sentient species (item W.3)	Alternative use of less stressful model or methods, or fewer animals (item W.4)	Lack of un-necessary duplication (item W.5)

2. Could any of the animal procedures described in this ACORP be replaced by computer models or *in vitro* techniques? Indicate below if such replacement is or is not possible, and provide a narrative on how you came to your conclusion.

3. Could a smaller, less sentient mammalian species or a non-mammalian species (e.g. poultry, fish, invertebrates) substitute for the mammals in any of the experiments planned? Indicate below if such substitution is or is not possible and provide a narrative on how you came to your conclusion.

4. Could a different animal model or different animal procedure that involves 1) less distress, pain, or suffering, or 2) fewer animals substitute for any proposed animal model or animal procedure planned? Indicate below if such replacement is or is not possible, and provide a narrative on how you came to your conclusion.

5. Does the proposed research unnecessarily duplicate previous work? Indicate below if the proposed work unnecessarily duplicates previous work and provide a narrative on how you came to your conclusion.

X. **Other Regulatory Considerations**. Complete items X.1, X.2, and X.3 below; then proceed to item Y.

1. **Controlled drugs**.

   a. Will all drugs used in animals and classified as controlled substances by the DEA or your state drug enforcement authority be stored in a double-locked cabinet, and be accessible only to authorized personnel in accordance with DEA regulations?
   ☐ Not applicable- no controlled drugs will be used. Proceed to item X.2.
   ☐ No. Please explain here, then go to item X.1.b.:
   ☐ Yes. Complete item X.1.b.

   b. List the controlled substances that will be used in vivo for this project, and include the building and room number where they will be stored.

2. Will any human patient procedural areas be used for these animal studies?
   ☐ No. Proceed to item X.3.
   ☐ Yes. Complete and attach Appendix 7, "Request to Use Patient Procedural Area;" then proceed to item X.3.

3. Will an explosive anesthetic or other explosive agent be used in any portion of these animal studies? (More info- item X.3)
   ☐ No. Proceed to item Y.
   ☐ Yes. Complete and attach Appendix 8, "Request to Use Explosive Agent;" then proceed to item Y.

Y. Please indicate which of the following Appendices are completed and attached. Do not attach blank appendices which are not applicable to this ACORP. Check with your IACUC to see if an optional Appendix 9, "Additional Local Information", is required.
☐ Appendix 1, "Use of Non-VA Animal Facility" (reference item N)
☐ Appendix 2, "Antibody Production" (reference item O)
☐ Appendix 3, "Test Substances" (reference item P)
☐ Appendix 4, "Antemortem Specimen Collection" (reference item R)
☐ Appendix 5, "Surgery" (reference item S)

☐ Appendix 6, “Special Husbandry and Procedures” (reference item V)
☐ Appendix 7, “Request to Use Patient Care Procedural Areas for Animal Studies” (reference item X)
☐ Appendix 8, “Request to Use Explosive Agent” (reference item X)
☐ Appendix 9, “Additional Local Information”

Z. **Certifications.** Signatures of the Principal Investigator(s), IACUC Chair, veterinarian, and R&D Committee Chair are mandatory; others may NOT sign for them. Copies (including FAX transmissions) of original signatures are fine, but stamps and digital graphics file reproductions are not acceptable. Note: Signatures must be less than one year old if this form is part of an application submission to VA Headquarters.

1. **Certification by Principal Investigator(s).**

To the best of my knowledge, I certify that the information provided in this Animal Component of Research Protocol (ACORP) is complete and accurate. I understand that IACUC approval is valid for one year only, that approval must be renewed annually, that every third year the IACUC must perform a new review of my protocol, and that I might be required to complete a newer version of the ACORP and provide additional information at the time of the triennial review. I also understand that IACUC approval must be obtained before I:

- Use additional animal species, increase the number of animals used, or increase the number of procedures performed on individual animals;
- Change procedures in any way that might increase the pain/distress category in which the animals are placed, or might otherwise be considered a significant departure from the written protocol;
- Perform additional procedures not described in this ACORP;
- Allow other investigators to use these animals on other protocols, or use these animals on another of my IACUC-approved protocols.

I further certify that

- No personnel will perform any animal procedures until they have been approved by the IACUC. When new or additional personnel become involved in these studies, I will submit their qualifications, training, and experience to the IACUC and seek IACUC approval before they are involved in animal studies;
- I will ensure that all personnel are enrolled in the institutional Occupational Health and Safety Program prior to their contact with animals;
- I will provide my after-hours telephone numbers to the VMU in case of emergency.

Name of Principal Investigator(s)	Signature	Date

6. **Minority Opinions (For IACUC Use).** IACUC members must be given the opportunity to submit minority opinions on this form. Enter any written minority opinions here (or attach separate pages labeled “IACUC Minority Opinion”). If there are no minority opinions, leave this space blank.

3. **Approval Signatures.**

a. To the best of their abilities, the undersigned have evaluated the care and use of the animals described in this ACORP in accordance with the provisions of the USDA Animal Welfare Act

Regulations and Standards, PHS Policy, the *Guide for the Care and Use of Laboratory Animals* and VA Policy, and find the procedures in this ACORP to be appropriate.

Name of Attending Veterinarian (VMO or VMC)	Signature	Date
Name of IACUC Chair	Signature	Date

b. The VA Research and Development Committee concurs with approval of the procedures described in this ACORP, and has approved the overall scientific merit of this project.

Name of R&D Committee Chair	Signature	Date